

## **REMARKS/ARGUMENTS**

The Office Action mailed July 15, 2004 has been reviewed and carefully considered. Claim 12 is canceled. Claims 1 and 15 have been amended. Claims 1-11 and 13-15 are pending in this application, with claims 1 and 15 being the only independent claims. Reconsideration of the above-identified application, as herein amended and in view of the following remarks, is respectfully requested.

In the Office Action mailed July 15, 2004, the amendment filed on May 4, 2001 is objected to as introducing new matter. More specifically, the Office Action states that the irradiance values for the power values introduces new matter. The specification is amended to cancel the alleged new matter.

The Amendment filed on February 14, 2003 is also objected to as introducing new matter. The Office Action alleges that the recitation of  $60 \text{ mW/cm}^2$  and the recitation of a cooling unit for cooling the surface to be irradiated. Support for  $60 \text{ mW/cm}^2$  is found on page 8, line 5, of the originally filed application. Support for the cooling unit for cooling the surface to be irradiated is found on page 10, last paragraph, and on page 18, lines 7-10, of the originally filed specification. Furthermore, page 12-13 of the original specification describe, with reference to Fig. 2, an embodiment of the present invention with a coolant unit (see last paragraph on page 12) and which applies irradiances of  $1\text{-}2 \text{ W/cm}^2$  (see page 13, line 16). Accordingly, a coolant unit and irradiances greater than  $60 \text{ mW/cm}^2$  are disclosed in the originally filed specification.

In view of the amendments and remarks, the objection to the amendments filed May 4, 2001 and February 14, 2003 as containing new matter should now be withdrawn.

Claims 1-11 and 13-15 stand rejected under 35 U.S.C. §112, first paragraph, as failing to provide an adequate written description of the claim limitations in the specification. The

Office Action alleges that the originally filed disclosure fails to discuss an irradiance of 60 mW/cm<sup>2</sup> or a cooling the irradiated area. As described above, the reference to an irradiance of 60 mW/cm<sup>2</sup> is found on page 8, line 5, of the originally filed specification and the reference to a cooling unit for cooling the irradiated area is found on page 10, last paragraph, and on page 18, lines 7-10, of the originally filed specification.

Claim 1 stands rejected under 35 U.S.C. §103 as unpatentable over Sigurdsson in view of Russell.

Claims 11, 13, and 14 stand rejected under 35 U.S.C. §103 as unpatentable over Sigurdsson and Russell in further view of Eastlund.

Claim 2 stands rejected under 35 U.S.C. §103 as unpatentable over Sigurdsson and Russell in further view of Edison.

Claims 3, 4, 6, 7, 9, and 10 stand rejected under 35 U.S.C. §103 as unpatentable over Sigurdsson and Russell in further view of Yoshizawa.

Claim 5 stands rejected under 35 U.S.C. §103 as unpatentable over Sigurdsson and Russell in further view of Hammer.

Claim 8 stands rejected under 35 U.S.C. §103 as unpatentable over Sigurdsson and Russell and Yoshizawa in further view of Edison.

Claim 15 stands rejected under 35 U.S.C. §103 as unpatentable over Sigurdsson in view of Lundahl and Lui.

The Examiner alleges that Sigurdsson discloses the method as recited in independent claim 1 except for use of a cooling device. The present invention relates to a method and apparatus for treating primary T cell mediated skin disorders. According to the invention, an optical radiation source emits in the wavelength range of 400-440 nm (see page 12, lines 7-8). Irradiance in the 300-

400 nm range is less than 21% of the irradiance in the 400-440 nm range (see page 17, lines 1-13). The preamble of independent claim 1 is amended to remove the term "cosmetic applications includes cosmetic tanning". The actual method step as presented in the prior amendment includes the limitation "using an irradiation device for treating primary T cell mediated skin disorders". That is, independent claim 1 as presented in the prior amendment and as currently presented requires the treatment of primary T cell mediated skin disorders and not the treatment of cosmetic applications.

Sigurdsson discloses the treatment of acne Vulgaris with visible light. As established in the previous responses and as indicated in the third paragraph on page 5 of the Office Action, treating Acne Vulgaris is a cosmetic treatment. Therefore, Sigurdsson fails to teach or suggest "using an irradiation device for treating a primary T cell mediated skin disorder", as expressly recited in independent claim 1.

Although we argued against Russell in the last response, Russell issued on September 18, 2001 after filing of the present invention and must therefore qualify as prior art under 35 U.S.C. §102(e). Under that section, prior art must be a patent or a published application by another filed in the United States before the invention by applicant. The present invention is a 371 of PCT/DE99/02364 filed on July 29, 1999, and which claims priority to DE 198 52 524.9, filed on November 6, 1998. However, Russell is based on an application filed on August 24, 1999, which is later than the filing date of both PCT/DE99/02364 and the priority document DE 198 52 524.9. Accordingly, Russell was not filed before the invention by applicant and therefore can not be considered prior art in the present application.

Even if Russell was considered prior art, Russell underscores that it is only known to treat *psoriasis* with ultraviolet light (see col. 9, line 25) and therefore does not teach or

suggest treating T cell mediated skin disorders with visible light in the recited wavelength ranges and at the recited irradiation levels.

Accordingly, independent claim 1 is allowable over Sigurdsson and Russell.

Independent claim 15 is amended to clearly recite that a primary T cell mediated skin disorder is treated and to recite that a cooling device is used as in claim 1. As described above, Sigurdsson fails to teach or suggest treating a primary T cell mediated skin disorder. As indicated by the Examiner in the Office Action, Lundahl discloses using visible light and ALA to treat acne. This still fails to disclose the recited irradiance levels and the treatment of primary T cell mediated skin disorders. Furthermore, neither Sigurdsson nor Lundahl disclose, teach or suggest "a first irradiance in a first wavelength range including 400nm to 440nm and a second irradiance in a second wavelength range including 300nm to 400nm, said first irradiance being at least 20 mW/cm<sup>2</sup> on the area to be irradiated and said second irradiance being less than 21% of said first irradiance on the area to be irradiated, such that the subject receives an irradiation dose within the range including 10 J/cm<sup>2</sup> to 200J/cm<sup>2</sup> from said first irradiance", as expressly recited in independent claim 1.

Lui discloses a method of treating psoriasis comprising identifying a psoriatic plaque with elevated endogenous porphyrin levels; treating the psoriatic plaque with visible light. Lui also discloses a method for identifying psoriatic plaque that is susceptible for treatment with visible light. Lui examined patients with other diseases see col. 6, lines 35 and Table II in col. 7. The other diseases included some primary T cell mediated skin disorders, e.g., atopic dermatitis. According to Lui, almost 50% of the psoriatic patients present an emission peak at 635nm which was not present in other diseases or in normal skin of the psoriatic patients. This fluorescence was found to be caused by Porphobilinogen Desaminase (col. 4, lines 65-66). Lui fails to teach or suggest that the treatment of

Lundahl could also be used for psoriasis because the results only show that less than 50% of the patients exhibit the emission peak. In addition, Lui fails to teach or suggest using the recited first and second irradiances to treat primary T cell mediated skin disorders because the results of Lui show that atopic dermatitis is not affected by visible light. Furthermore, Lui also fails to teach or suggest the claimed first and second irradiance.

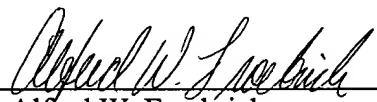
In addition, the attached article shows that symptomless skin of psoriasis patients is not normal by comparison to healthy skin from non-psoriatic persons. Accordingly, those skilled in the art would not combine the teachings of Lundahl and Lui to treat psoriatic patients. Even if they were combined, the teachings of Sigurdsson, Lundahl and Lui fail to teach or suggest the recited first and second irradiance of independent claim 15. Furthermore, none of the reference of record disclose using a cooling unit for cooling an area to a irradiated.

Dependent claims 2-11 and 13-14, being dependent on independent claim 1, are deemed allowable for the same reasons expressed above with respect to independent claim 1.

The application is now deemed to be in condition for allowance and notice to that effect is solicited.

Respectfully submitted,

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Dated: November 15, 2004